



RESEARCH PROTECTIONS UPDATE



News and Comments on the Protection of Human Subjects in Navy and Marine Corps Research

Volume 13, Number 1

Winter/Spring 2023

DIRECTOR'S CORNER

Welcome to the 2023 winter/spring issue of the Research Protections Update (RPU)! I am pleased to introduce this edition with its special emphasis on Administration. As found in the Merriam Webster Dictionary, the definition for Administration includes, but is not limited to: "to manage or supervise the execution, use, or conduct of, to provide or apply, to furnish a benefit, and to manage affairs." Administration is clearly a critical and dynamic function of the DON HRPP, and the many Human Research Protection Programs of which DON HRPP conducts oversight. This issue includes an overview of Administration from the DON HRPP Administrator, Cindy Mazowieski, a Question and Answer piece focused on Administration experiences and best practices with two DON HRPP commands, and an introduction to DON HRPP activities that I am proud to have brought to the forefront of our Administrative efforts. These include our first Quality Assurance (QA) survey, a new DON HRPP Logo, and of course, our first ever Business Meeting and Knowledge Exchange (BMAKE) 31 May and 1 June. It is my hope that the efforts of the past, and of course the efforts of future activities, "furnish a benefit" for You - our community of Institutional Officials, Human Research Protection Program Administrators, Institutional Review Board (IRB) Chairs and members, Principal Investigators, the Warfighters, and anyone involved with or impacted by the ethical pursuit of human subjects research. Human subjects research protections is no easy task, but it deserves the best possible execution and "conduct of." I hope you will join us as we continue to strive toward being the best Administrators we can be, and I hope to see your feedback in our QA survey and at the DON HRPP BMAKE!

Behind the Scenes

The Department of the Navy Human Research Protection Program (DON HRPP) Administrator works behind the scenes, completing many different tasks as a facilitator in support of the DON HRPP. My name is Cindy Mazowieski and I have served as the DON HRPP Administrator for 14 years, during which I've gained extensive knowledge about compliance, training and education, quality assurance, and so much more. This has given me the ability to see key aspects of the program as a whole, rather than independent functions. This perspective has allowed me to aid the Director and Deputy Director in promoting the DON HRPP mission, and I thought it may be helpful to share this perspective with the DON HRPP community.

As the DON HRPP Administrator, I work closely with the Directors, assisting each of them in implementing their vision for the program. I help to maintain program continuity amidst its evolving environments, and work collaboratively with the
(continued on page 2)

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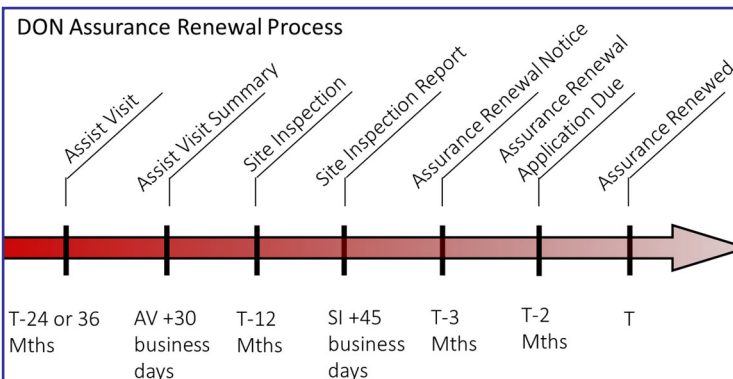
Behind the Scenes (continued from page 1)

Office of Naval Research (ONR) 0343, which supports DON HRPP. Whether an element originates with the Bureau of Medicine and Surgery (BUMED) office, or ONR 0343, I review each item to ensure it meets the DON HRPP requirements and each Directors' standards. I also meet and forge connections with fellow administrators from other commands by assisting with their HRPP administrative needs.

The DON HRPP general mailbox is the program's source for sending and receiving official communications. The familiar e-grams, official responses, assurance correspondence, and visit notices are sent via this mailbox. As the program administrator, I manage the DON HRPP general mailbox regarding these and other various inquiries and topics. Any communications received in the DON HRPP mailbox are triaged, forwarded and shared as appropriate for response, and filed. Likewise, all outgoing official DON HRPP correspondence is retained for record. Records are a key requirement and a product of the program processes.

DON HRPP policies and procedures establish and maintain administrative processes. Standardizing procedures has ensured that all assurance packages are successfully processed for signature by the Navy Surgeon General (SG); all official visit announcements are sent in a timely manner for command notice; each site inspection report and assist visit summary are sent in a clear format; each Component-Level Administrative Review (CLAR) is processed for Director review; all Human Research Protection Official (HRPO) and Exemption Determination Official (EDO) designations are processed for Director approval and appointments are recorded; and all other aspects of the command assurance are maintained on file. The program administrator manages and tracks each process through to completion via a tasker management system.

The assurance process is one of the largest administrative processes for the program but is not limited to the



application submission. The assurance renewal process also includes the conduct of assist visits and site inspections, as shown in the "DON Assurance Renewal Process" graphic. Throughout each of these events, the DON HRPP Administrator works behind the scenes from the announcement notice to the closure of each visit, and from the assurance reminder notice to sending the SG approval of that assurance renewal to the command.

For any well-organized program, clear, concise, and up-to-date templates are a must for ensuring information is recorded and presented in an efficient manner. One of my key roles as the DON HRPP Administrator is to maintain program templates for use such as assurance applications, Institutional Agreements for Institutional Review Board (IRB) Review (IAIRs), Individual Investigator Agreements (IIAs), as well as updating DON HRPP briefings for Director meetings with the SG, Deputy SG, Special Assistant Human Research Program (SAHRP), and command Institutional Officials (IOs).

Throughout the years I have seen many changes. The role of the DON HRPP Director is held by military personnel and thus is a position subject to periodic rotation. This can be both challenging and rewarding. With each new Director comes the process of introducing the DON HRPP and its administration methods to a set of fresh eyes. This opportunity to view DON HRPP with new vision is invaluable to the ongoing development of the program. Over the years, I have had the pleasure of working with numerous great Directors who have brought new ideas and insights to the DON HRPP.

I am always excited to see all the new developments taking place and have the opportunity to work on special projects and events. I look forward to the many upcoming endeavors for administration in the DON HRPP and continuing to contribute to this vital Navy program.

By Cindy Mazowieski

Ms. Mazowieski has been the DON HRPP Administrator for 14 years, providing her knowledge, expertise, and support to the staff and leadership team.



The DON HRPP Business Meeting and Knowledge Exchange

On 31 May and 1 June 2023, the Department of the Navy Human Research Protection Program (DON HRPP) will proudly present a DON human research protections business meeting and knowledge exchange (BMAKE). The event will be held via hybrid format, both online and in-person at the Bureau of Medicine and Surgery (BUMED) Defense Health Headquarters (DHHQ) in Falls Church, VA.

Speakers Include: Senior Navy Leadership, Department of Defense (DoD) Office of Human Research Protections (DOHRP), DON HRPP team members, component HRPP Directors, Subject Matter Experts such as representatives from the Navy Survey Program Office and more!

Topics Include: An overview of Navy research with human subjects, DON HRPP's engagement in oversight and monitoring, updated processes and procedures, the latest templates for DON Institutions, surveys, working with other services, Office of Naval Research (ONR) funding, best practices, and more. Attendees will also have an opportunity to engage in facilitated networking. See agenda on next page!

Purpose: To connect with members of the HRP community, discuss guidance on topics of interest, network with peers, learn from DON HRPP, hear from DON Leadership, and engage experts in the field.

Attendees: DON Leadership, DON Institutional Officials, HRPP members such as Points of Contact (POCs), Institutional Review Board (IRB) Chairs/Vice Chairs/Admins, Principal Investigators (PIs), researchers, DON Human Subjects Research (HSR) affiliated folks, and DoD HRP and Component Office of Human Research Protections (COHRP) leadership.

Logistics: RSVPs are required to attend the event, both in-person and virtual. Information about attending the event, such as hotels around DHHQ, the agenda, and read-ahead/pre-viewing material, is available on milSuite.

Post Event Access to Materials: The event will be recorded and posted to milSuite.

In-Person Attendees

Food: Coffee and light snacks will be provided (donation welcome). Lunch will be available for purchase. A no host social will take place at the conclusion of Day 1 on 31 May at a restaurant near DHHQ. Details are provided in the in-person confirmation notice.

Hotels, Transportation, Parking: Please see additional information on milSuite or after you RSVP.

If you have any questions, please contact the POC for this event: Nancy Dawood
Nancy.d.dawood.civ@health.mil

THE DON HRPP BMAKE CURRENT AGENDA

Day 1	Session
0900-0925	Welcome, Overview, and Comments from Senior Navy Leadership
0925-1025	DON HRPP Overview, Updates, and Meet the DON HRPP Team
1025-1055	DON HRPP Administrator Overview
1100-1120	Senior Navy Leadership Remarks
1120-1130	Break
1130-1200	DON HRPP Training and Education Overview
1200-1230	DON HRPP Quality Assurance/Quality Improvement Overview
1230-1330	Lunch
1330-1400	Best Practices across DON Command HRPPs
1400-1500	Subject Matter Experts View on HRPP Hot Topics
1500-1510	Break
1510-1600	Navy Survey Program Office
1610-1650	DON HRPP Site Inspections/Assist Visits: Processes/Expectations and Findings
1650-1700	Wrap up and Closing Remarks

Day 2	Session
0900-0930	Welcome and Overview with Senior Navy Leadership Remarks
0930-1030	Overview of the Research Landscape with BUMED and the ONR
1030-1100	DoD Office for Human Research Protections
1100-1110	Break
1110-1230	Air Force, Army, Defense Health Agency, Uniformed Services University Panel
1230-1330	Lunch
1330-1400	US Marine Corps HRPP
1400-1430	E-IRB with an Expert
1430-1500	Special Topics
1500-1510	Break
1510-1540	Funding Opportunities with the ONR
1540-1555	Mapping the DON HRPP Research Landscape
1555-1645	Facilitated Networking
1645-1700	Wrap up, Appreciation, and Closing Remarks by Senior Leadership

HIGHLIGHTS: Administrative Processes at the Navy Medicine Operational Training Command (NMOTC) and the Naval Medical Research Command (NMRC) HRPPs.

CAPT Carrie H. Kennedy at NMOTC has answered the questions below.

Question: What's the administrative structure/organization of the command's HRPP (including the IRB)?

CAPT Kennedy: The Navy Medicine Operational Training Command's (NMOTC) Scientific and Ethical Review Committee (SERC) consists of a Chair (who simultaneously serves as NMOTC's Research Coordinator), Vice Chair, Detachment Research Coordinators (DRCs; one for each of NMOTC's detachments), Exempt Determination Officials (EDO), Statistician, Non-scientist Member, Research Scientists, and a Senior Enlisted Representative. The committee reports directly to the NMOTC Institutional Official/Commanding Officer. For any submission that cannot be dispositioned by an NMOTC EDO, the protocol is forwarded to our IRB of record at NAMRU-Dayton.

Question: What tools do you use to manage your HRPP administrative processes and approvals at your command?

CAPT Kennedy: NMOTC SERC relies on EIRB for the majority of administrative processes related to protocol submissions.

Question: How does the command handle the HRPP's administrative needs?

CAPT Kennedy: Because there are no personnel specifically assigned to NMOTC SERC, the committee uses command administrative personnel with other roles and responsibilities within the organization. For administrative needs, NMOTC utilizes the Administrative Assistant and Operations Supervisor at NMOTC Headquarters to assist with various administrative tasks. These tasks consist of organizing/communicating committee meetings, compiling meeting minutes, generating appointment letters, communicating training requirements and assisting with DON HRPP visit preparation. DON HRPP also includes the NMOTC HQ Operations Supervisor on general correspondence directed to the NMOTC HRPP POC/SERC Chair & Vice-Chair which provides another layer of support to assist with timely responses and distribution of information. By assisting with the various tasks mentioned above, the NMOTC Research Program personnel (SERC Chair, Vice-Chair, Research Psychologist, etc.) can focus on supporting operational research and adherence to the principles that guide research at NMOTC and its detachments.

Question: What challenges have you experienced?

CAPT Kennedy: The NMOTC SERC faces two challenges. The first is that all members of the committee have other primary duties and the committee depends on active duty

billets being continuously filled; the SERC is a collateral duty for all. This presents challenges related to prioritization, turnover, and a steep learning curve for new members who have no prior IRB experience. The second has been the adoption of EIRB, which has presented a steep learning curve for the committee.

Question: What were the resolutions?

CAPT Kennedy: Our first challenge is a continuous one, but was compounded over the past two years due to 2 of our 3 aerospace experimental psychologist billets being unfilled for much of that time (the heart of the committee). Approximately two months ago these billets were filled and the committee is already experiencing some relief and the ability to further refine processes. The second challenge remains a work in progress as the current SERC members learn the intricacies and functionality of EIRB. This will work itself out over time as we gain more experience and improvements are made to the user interface of EIRB.

Question: What things have been done in the last few years to improve efficiency of HRPP processes?

CAPT Kennedy: Two processes stand out. First, in January 2022, NMOTC SERC adopted EIRB to process all submissions. Prior to using this system, protocol reviews, correspondence, and approvals were managed via email and/or hard copies between researchers and members of NMOTC SERC. While the move to EIRB has come with a learning curve, the ability to track, share, and digitally record all research protocol activities with SERC membership and DON HRPP in real time has allowed for a more streamlined and scalable process, as well as eased time-consuming administrative requirements. Most notably, the ability to search and quickly retrieve all research protocol documentation in a single system makes it much easier to track studies and ensure quality and compliance. Second, NMOTC SERC has made a concerted effort not to have any single point of failure. We have added a second scientific reviewer, taking some of the pressure off of the lone reviewer, and enabling both to spend more time working with individual researchers on their study designs. We are also in the process of adding a second Exempt Determination Official (EDO). This will improve both scientific review and EDO determination turn-around times.

DON HRPP appreciates CAPT Carrie H. Kennedy providing insight to NMOTC administrative processes.

(See page 6 for NMRC questions and answers)

HIGHLIGHTS: Administrative Processes at the Navy Medicine Operational Training Command (NMOTC) and the Naval Medical Research Command (NMRC) HRPPs. (cont'd)

Ms. Terri Brantley at NMRC has answered the questions below.

Question: What's the administrative structure/organization of the command's HRPP (including the IRB)?

Ms. Brantley: NMRC has a unique structure for human research management. The IRB leadership (Chair/Vice Chairs) is typically and primarily comprised of scientific members from one of our research directorates. The HRPP's administrative arm rests completely in one of the administrative directorates, Research Services Directorate (RSD). RSD supports two primary components: Research Support Services (the Office of Research Administration, Animal Medicine, and Veterinarian Pathology) and Acquisition and Program Management (Naval Advanced Medical Development, Legal and Intellectual Property, Office of Business Partnerships and the DoD Bone Marrow Program). The Office of Research Administration (ORA) manages all the administrative aspects of the human research – SRB, IRB, administrative collaborations, etc. The Director, RSD, also serves as the Command's Research Integrity Officer. This arrangement allows for seamless collaboration with our legal teams and Office of Business Partnerships to obtain agreements or advice on actions.

Question: What tools do you use to manage your HRPP administrative processes and approvals at your command?

Ms. Brantley: Our Command's primary tools rest in the Microsoft Office Suite. However, our greatest assets are our templates and checklists that help the team to navigate the HRPP processes. The Office of Research Administration (ORA) in collaboration with the IRB and SRB leadership develops and updates these tools to assist the investigators and Board members in reporting, reviewing and approving research.

The ORA team also developed Standard Operating Procedures (SOPs) for virtually all administrative processes from triaging submissions to sending them to DON HRPP for higher level review. I have found that although this process is initially painful and sometimes tedious, it is exponentially helpful in guiding ORA members in next steps. As processes change, so too does the SOPs. For example, prior to April 2020, most of ORA processes were paper-based routings. We would receive paper submissions, route them to reviewers, submit them to the Commander for approval and submit paper and e-versions to investigators for their files. An office remodel in January 2020 demanded that we re-think how everything could be done without paper exchanges since we couldn't occupy the office for six weeks. We turned everything into electronic submissions, and it allowed us to maintain a complete e-fingerprint of protocol lifecycle. This was an amazing dress rehearsal for what would become an operational necessity due to the COVID pandemic.

Also, in 2019, the Command introduced the use of

Global Electronic Approval Routing System (GEARS) which was a way of routing and tracking actions to various users, including the Commander and Deputy Commander. When we were still sending actions to the Commander for approval, this system allowed us to track the items directly to individuals (and tell how long they had it in their possession) and upload and download documents with few errors or hiccups. It was definitely a game-changer. It fully eliminated the old fashion need to call office to office to locate routing ORA folders.

Question: How does the command handle the HRPP's administrative needs?

Ms. Brantley: The ORA team is the administrative hub for the HRPP/IRB's needs. We triage, file, share communications, and retain records. In that way, we are the primary (longstanding) core for administrative needs. Our resourcefulness is further augmented with institutional knowledge. LOL! I will have been at NMRC 19 years in July 2023. So, I have been around and can remember how things are done/ why they are done and what worked and what didn't work so well.

Question: What challenges have you experienced?

Ms. Brantley: I think one of the biggest challenges has been losing longstanding IRB leadership. NMRC was fortunate to have had an IRB Chair who served for close to five years and two Vice Chairs who served for four years and one Vice Chair who served the command for over 20 years. That institutional knowledge, know-how, mentorship and credibility within the HRPP community is a huge hurdle to overcome. Another hurdle is the loss of seasoned ORA administrative team members. The IRB Administrator left for newer pastures after five years of service. Again, that is a huge loss to sustaining a program.

Question: What were the resolutions?

Ms. Brantley: The Commander has appointed eager, diligent leaders who take the IRB seriously. I think these skills combined with educational opportunities will develop leaders who serve with the same effectiveness, and who will develop the same ability to mentor other IRB members and investigators in the protection of participants in research. ORA has hired a capable IRB Administrator who hails from NIH and brings with her the capacity to impact the program in greater ways in the years to come.

Question: What things have been done in the last few years to improve efficiency of HRPP processes?

(NMRC continued on page 8)

39th Navy Surgeon General Retires



Rear Adm. Bruce Gillingham retired as the Navy's Surgeon General on 27 March 2023. Rear Adm. Gillingham celebrated his 40 years of active-duty service during the retirement ceremony. Rear Adm. Gillingham served as the 39th Surgeon General for the Navy. Through his accomplishments, Rear Adm. Gillingham is highly respected throughout the DoD. "During his tenure as Surgeon General, Gillingham led approximately 44,000 Navy medical personnel through the U.S. Navy Bureau of Medicine and Surgery's (BUMED) most comprehensive transformation since World War II."

By Ed Gulick—Rear Adm. Bruce Gillingham, Retires as Navy's 39th Surgeon General—Cited 3.27.2023 DVIDS - News - Rear Adm. Bruce Gillingham, Retires as Navy's 39th Surgeon General (dvidshub.net)

DON HRPP wishes Surgeon General Rear Adm. Bruce Gillingham Fair Winds and Following Seas. We are grateful for his dedicated service.

DON HRPP News!!!

DON HRPP QA SURVEY

https://usnavy.gov1.qualtrics.com/jfe/form/SV_7UuzgkLF6FIOWbk

DON HRPP has developed its first ever Quality Assessment (QA) Survey to assess the DON HRPP performance in carrying out its functions of oversight, monitoring, training and education, as well as provide an opportunity for feedback. DON HRPP is interested in what we are doing well, and what we can improve on. Results will be aggregated and are intended to shape current and future DON HRPP efforts.

This survey is anonymous unless you provide identifying information in the comments, should take approximately 10-15 minutes to complete, is voluntary, and may be stopped at any time. The survey closes 25 May 2023.

Due to contract laws outside of our control, we may not ask contractors to complete the survey at this time. We are working towards a contractor friendly version and will share when this becomes available.

This survey was deemed not Human Subjects Research by the Navy Survey Office and has been approved for use (approval number NSPM23.11).

If you have any questions about the survey, please reach out to nora.d.livengood.ctr@health.mil

We appreciate your time and feedback!

DON HRPP Welcomes RDML Guido Valdes as the New SAHRP



Rear Adm. Guido F. Valdes has been appointed as the new Special Assistant to the Surgeon General of the Navy for Human Research Protections (SAHRP).

Rear Adm. Valdes is a native of San Juan, Puerto Rico. He holds a Bachelor of Science in Biology from the University of Miami, Florida. He earned his Doctor of Medicine from the University of Miami School of Medicine as a Navy Health Professions Scholarship recipient and upon graduation he received his commission in 1992. His professional training includes transitional internship at the National Naval Medical Center Bethesda and emergency medicine residency at Naval Medical Center Portsmouth.

Operationally, he served as officer-in-charge of the Shock Trauma Platoon/Forward Resuscitative Surgical Site at Camp Korean Village in Al-Anbar province, Iraq during Operation Iraqi Freedom; officer-in-charge, Fleet Surgical Team Six; force surgeon, Riverine Group One; executive officer, Role 3 Multinational Medical Unit, Kandahar, Afghanistan during Operation Enduring Freedom; and force surgeon, U.S. Naval Forces Central Command/ U.S. 5th Fleet.

He has served in various positions throughout Navy Medicine to include general medical officer, Branch Health Clinic Gaeta, Italy; staff emergency physician, U.S. Naval Hospital Naples, Italy; U.S. Naval Hospital Rota, Spain; and Naval Medical Center Portsmouth; executive

officer, Naval Hospital Pensacola; commanding officer, Naval Health Clinic Corpus Christi; and deputy commander, Naval Medical Forces Atlantic.

Rear Adm. Valdes assumed duties as commander, Naval Medical Forces Pacific, 20 May 2022. He has oversight of ten Navy Medicine Readiness and Training Commands on the West Coast and Pacific Rim as well as Navy Medicine's eight global research labs. Valdes also serves under the Defense Health Agency as the director of the San Diego Medical Market where he oversees the delivery and integration of healthcare at Naval Medical Center San Diego and Naval Hospital Camp Pendleton.

Rear Adm. Valdes is qualified as a Fleet Marine Force Warfare Officer. His personal decorations include the Legion of Merit (two awards), Meritorious Service Medal (four awards), Navy Commendation Medal (two awards), Navy Achievement Medal and various other unit and campaign awards.

Rear Admiral Guido F. Valdes, America's Navy, 20 July 2022 (<https://www.navy.mil/Leadership/Flag-Officer-Biographies/BioDisplay/Article/3099467/rear-admiral-guido-f-valdes/>)

NMRC Administrative Processes

(continued from page 6)

Ms. Brantley: One of the biggest changes we've implemented is updating our local Instruction to agree with the DoDI and the common rule to allow the IRB to be the approval authority. Once the IRB approves research at NMRC, the research can be implemented. There is only one exception to this rule: initial approvals of research. In this case, the Commander still provides implementation authorization for work utilizing Command personnel and resources prior to initiating research. It has been a huge asset to efficiency for all previously approved actions.

DON HRPP appreciates Ms. Terri Brantley providing insight to NMRC administrative processes.

Introducing the New DON HRPP Logo



The Department of the Navy Human Research Protection Program (DON HRPP) is proud to present its new logo. This logo, within the limits and parameters required by public affairs and communication guidance, incorporates the unique elements that make up the DON HRPP and was created to represent the program as maximally as possible. To learn more about this new logo please continue reading below!

Colors. The color palette selected brings in blues for water (Navy), green for land (Marine Corps), scarlet for both the Marine Corps and Red Cross/medical care, and gold for our Naval heritage. The Blue & Green Quadrants have dual impact, representing both land and sea, as well as a symbol of Navy and Marine Corps teamwork that forms the force that ensures naval maritime superiority.

Red Cross. Internationally recognized as a symbol of medical care representing the Navy Medicine mission. Long associated with medicine, blood/life, healing, and blood stripe on the Marine Corps Uniform. This symbol also reflects DON HRPP as a program of SG responsibility.

Anchor. The Anchor has long been a symbol of the U.S. Navy.

Golden Rope. The gold outer rope is our bond to Naval tradition and is a symbol of Navy officers representing their personal and professional integrity.

Inner Red & Gold Rings. Official USMC colors and enduring support to their mission.

White Type & Icons. Represents the Navy's focus on mission, purity and unity.

Inner Symbols.

Shield: The shield (top center) represents protection of human subjects, which is at the heart of DON HRPP.

Handshake: The handshake (top left) represents collaboration- between the BUMED and ONR (which constitute DON HRPP) as well as DON HRPP and the Commands. DON HRPP strives to approach oversight and monitoring in a collaborative manner.

Aircraft and Carrier: The aircraft (top right) and carrier (bottom left) represents operational forces research and the Warfighter.

Microscope and Caduceus: The microscope (bottom right) and *Caduceus* (bottom center) represents scientific and operational medicine research.

Globe. The globe that these symbols rest on reflects the international scope of the human subjects research that DON HRPP oversees and monitors.

You may also notice that BUMED, and therefore DON HRPP, materials have started to utilize the below signal flags. These flags are CHARLIE MIKE and represent Rendering Assistance.



As noted in the 2023 BUMED Almanac "In an era long before the advent of satellites, cell phones, and radios, seafarers used a communication system based on flags and pennants.

Transmitting messages over long distances is called Semaphore, and these visual signals enabled ships to communicate with other ships at sea. For more than 30 years, Navy Medicine has used Semaphore Flags part of the International Code of Signals to convey our posture and activity within the Fleet. In 1987, we adopted the motto "Charlie Golf One" to signify Navy Medicine was "Standing By, Ready to Assist." Following the attacks on September 11th, Navy Medicine shifted to "Charlie Papa" meaning that we were "Steaming to Assist"

in times of crisis. In November 2021, we shifted our colors to reflect our active mission of "Rendering Assistance" to our warfighters. We are keeping them in the Fight and ensuring they are operationally ready for that next mission. In Semaphore, Rendering Assistance is communicated by an Answer Pennant and two Flags -- "Charlie" and "Mike." These signal flags will help guide us forward as we continue to deliver operational medical capabilities to our Sailors and Marines."

Welcome to DON HRPP!



Monai Carter is an Executive Assistant for the ONR Code 34 program that supports DON HRPP. Ms. Carter joined ONR in November 2022. She is a Prince Georges County, Maryland native born in Washington DC. She comes over from the Defense Health Agency where she supported the J5 Analytics and Evaluation Team as well as J3 Clinical Health Women's Division. She has a bachelors in Criminal Justice and Criminology from Purdue University. Prior to contracting, she was a federal civilian 4.5 years on Andrews Air Force Base supporting the 316th Squadron as Child Youth Program Assistant/Admin. She has over 6+ years working in the federal government and supporting high level clients.



Ms. Jyothsna Pabba is Human Subjects Research Compliance Specialist at DON HRPP. Jyothsna joined ONR in November 2022 and specializes in review and evaluation of initial and post approval regulatory reviews to be in compliance with Federal, Department of Defense (DoD), and U.S. Army Regulations, policies and guidelines. She has earned a Bachelor of Science Degree in Microbiology from Kakatiya University, India. Prior to joining ONR, Jyothsna served as Human Subjects Protection Scientist for five years as a contract support staff for Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), U.S Army Medical Research and Development Command (USAMRDC). In this position Jyothsna conducted regulatory reviews of complex human subject research protocols, providing subject matter expert by providing guidance, recommendations to OHRO.

Fair Winds and Following Seas

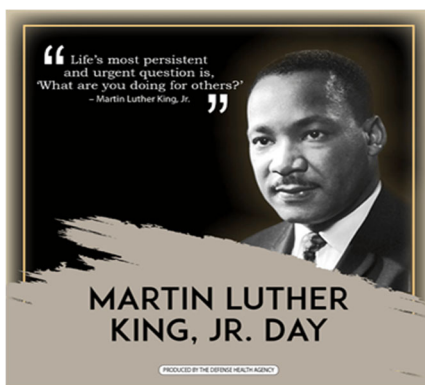
DON HRPP wishes CAPT Christopher Kurtz Fair Winds and Following Seas and appreciates all the support he provided to the program in his service as the Special Assistant to the Surgeon General of the Navy for Human Research Protections (SAHRP).

Special Observances

1. Martin Luther King Jr. Birthday—January 2023
2. National African American/Black History Month—Feb 2023
3. Women's History Month—March 2023
4. Asian American and Pacific Islander Heritage Month—May 2023
5. Jewish American Heritage Month—May 2023
6. National Armed Forces Day—20 May 2023
7. National Pride Month—June 2023
8. Juneteenth—19 June 2023

For more ways to celebrate diversity, please see observance materials provided by the Defense Equal Opportunity Management Institute at <https://www.defenseculture.mil/>

Martin Luther King Jr. Birthday



Black History Month



Women's History Month



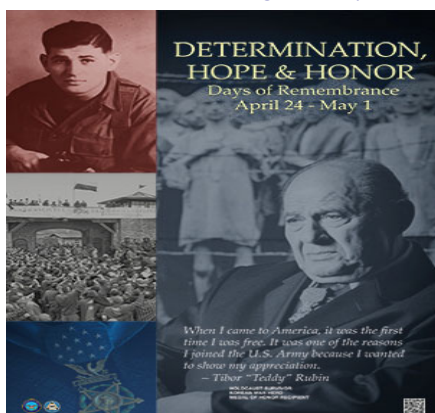
National Armed Forces Day



Asian American Pacific Islander Heritage Month



Jewish American Heritage History Month



National Pride Month



Juneteenth



RPU CONTRIBUTION SOUGHT

Have a "Good News" story or picture from your Research Protection Program? Have a best practice you want to share with others? Consider sharing it with the DON Research Protection community! DON HRPP offers an open invitation for submission of material for potential inclusion in the *Research Protections Update* newsletter. Please send your research news, success stories, tips, pictures, lessons learned, or other material related to the ethical conduct of human research to usn.ncr.bumedfchva.mbx.don-hrpp@health.mil to be reviewed and shared in the DON HRPP RPU.

DON HRPP FUN — UNSCRAMBLE THE RESEARCH TERMS

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Jonise C. Handy-Richards, CCRP, Editor